

Appln. No.: 10/054,067
Amendment Dated April 26, 2004
Reply to Final Office Action Dated November 26, 2003

CV0110A

Remarks/Arguments:**1. Status of Application and Interview Summary**

In the Final Office Action mailed February 26, 2004 (hereafter "Office Action"), claims 3-13 were rejected, and previous rejections were withdrawn. In the present amendment, claims 4 and 9 are amended, and claims 3-13 remain pending.

The applicants appreciate the courtesy shown their representatives Pamela Politis and Basil Krikolis during a telephone interview on March 10, 2004 with Examiner Hines and her Supervisor, Lynette Smith. During the telephone interview, the representatives, along with Subramanian Iyer, Ph.D., the research director of Arkion Life Sciences, assignee of the present application, discussed the nature of the invention and distinguishing aspects of the invention. As a result of the interview, the Examiner and Supervisor indicated that a claim language amendment consistent with common usage of the term immunogen would put the claim in condition for allowance. The Examiner and Supervisor specifically noted the unusual syntax of "infection from the immunogen" in claim 9. The applicants have carefully considered the Examiners and Supervisors' comments and have amended the claims accordingly.

Specifically, claim 9 has been amended to recite that the egg-producing animal is administered a vaccine "comprising at least one immunogen from an organism, and wherein the subject animal is free of infection from the organism." This amendment is supported in the specification at page 13, line 25-page 15, line 15.

In a follow-up phone message from Examiner Hines to Pamela Politis, the Examiner requested that the applicant explain the claim language "at least one organism" in view of the specification. In response to this request, the applicant notes that the hyperimmunization process, as recited in the claims, can be conducted using a single immunogen or organism. The hyperimmune response is elicited in an animal upon multiple inoculations of the same immunogen. The immune system responds to multiple challenges by the same immunogen by producing a variety of antibodies and immune factors associated with the hyperimmune response. Additionally, the antibodies and immune factors generated in response to each sequential challenge to the immune system in the hyperimmunization process are at a different stage of maturity. This variation in system maturity contributes to the hyperimmune state.

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The hyperimmunization process is described in the specification as including "administering an initial immunization, followed by periodic boosters with sufficiently high doses of specific immunogens or mixtures of immunogens." Page 6, lines 28-30. Accordingly, the process as claimed is enabled in that the hyperimmune response can be achieved via multiple inoculations of the same, single immunogen.

2. Objections

Claim 4 and the specification were objected to because of misspelling. Claim 4 and the specification have been amended herein to correct for the misspelling. Withdrawal of the objections is respectfully requested. Additional minor errors were noted in Table 1 of the specification and in the corresponding language set forth in claim 4. These errors are considered obvious errors that do not constitute new matter because one skilled in the art would not only recognize the existence of the errors, but would also recognize the appropriate correction.

3. Claims Rejections under 35 U.S.C. § 112(2)

Claim 4 was rejected for the lack of antecedent basis. Claim 4 has been amended herein to provide for sufficient antecedent basis. Withdrawal of the rejection is respectfully requested.

4. Claim Rejections under 35 U.S.C. § 102(b)

A. **U.S. Patent No. 5,601,823**

Claims 3, 6, and 8-9 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,601,823 issued to Williams et al. (hereafter the "'823 Patent"). The Office Action noted that the '823 Patent was directed to treating animals and humans infected with toxins from *Clostridium* with antibodies obtained from the egg of animals immunized against *Clostridium* toxins. As discussed in the interview, the '823 Patent does not appear to disclose or teach an egg product that is able to treat diarrhea in a subject animal that is not infected with *Clostridium* or *Clostridium* related toxins.

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The present invention is distinguishable over the '823 Patent because in the present invention, the subject animal is not suffering from an infection related to any of the contents of the vaccine which was administered to the egg-producing animal. The egg-product of the present invention addresses non-bacterial induced diarrheal symptoms, or diarrheal symptoms induced by an organism other than one whose antigens are included in the vaccine on the other hand, the '823 Patent is directed at promoting an antigen-antibody reaction to attack the cause of the bacterial-induced diarrhea in the subject animal. As such, the '823 Patent does not disclose or suggest a method of treating and preventing diarrhea in a subject animal that is free of infection from an organism. The amendment to claim 9 clarifies that the subject animal is not infected with a bacterium, or other organism, causing the diarrheal symptom. In view of the discussion during the telephone interview, and the above remarks, the applicants submit that the claims are allowable over the '823 Patent and respectfully request withdrawal of the rejection.

B. U.S. Patent No. 4,748,018

Claims 3-4 and 8-9 were rejected under were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 4,748,018 Issued to Stolle et al. (hereafter the "'018 Patent"). The '018 patent is directed at passive immunization against a condition caused by an antigen (see the '018 Patent, col. 3, lines 15-18). Claim 9 of the present application states that the subject animal is free from infection from any organism used to illicit an immune response in the hyperimmunized animal. Accordingly, the diarrheal symptoms can NOT be caused by the antigen as described in the '018 Patent.

Additionally, the '018 Patent is directed at treating infection (i.e. snake bite) or preventative treatment via passive immunization (col. 7, lines 3 - 17), with no apparent disclosure of treating diarrheal symptoms, as set forth in the present application. The present invention is not directed to passive immunization. In contrast to passive immunization, the subject animal suffers from symptoms completely unrelated to immunogen infection, i.e. diarrhea caused by castor oil ingestion. (See the specification, Example 2, pgs. 15 - 18). Because the '018 Patent does not disclose or teach treating diarrhea, or treating any symptoms where the sufferer is not infected with the organisms administered to generate a passive immunization, it does not anticipate or render obvious the present invention. Withdrawal of this rejection is respectfully requested.

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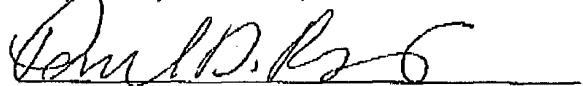
5. Claims Rejections under 35 U.S.C. § 103(a)

Claims 5 and 10-11 were rejected as obvious the '823 Patent and U.S. Patent No. 5,593,972, issued to Welner et al. and claims 6-7 and 12-13 were rejected over these patents in view of U.S. Patent No. 5,420,253 issued to Emery et al. Because neither the '972 Patent or the '253 patent disclose or teach treating diarrhea in a subject animal that is free of infection by an organism, or from an immunogen-encoding DNA construct, they do not address the failings of the disclosure of the '823 patent discussed above. Accordingly, applicants respectfully request withdrawal of these rejections.

6. Conclusion

In view of the foregoing amendments and remarks, applicants submit that this application is in condition for allowance and respectfully request early and favorable notification to that effect. If it would expedite prosecution, the Examiner is invited to confer with the undersigned representatives.

Respectfully submitted,



Basil S. Krikellis, Reg. No. 41,129
Pamela D. Politis, Reg. No. 47,865
Attorney and Agent for Applicants

PDP

Attachments: Request for Extension of Time
Fee Transmittal

Dated: April 26, 2004

☒ P.O. Box 1596
Wilmington, DE 19899
(302) 778-2500

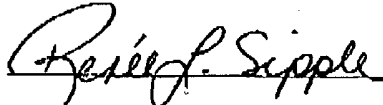
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April 26, 2004



Renee L. Sipple